

Bensinger, DuPont & Associates

Management Consultants for a Drug-Free Workplace

BDA

November 26, 2001

CORPORATE OFFICES

One Central Plaza
11300 Rockville Pike
Suite 713
Rockville, Maryland 20852
(301) 881-8210
FAX (301) 816-1085

20 North Wacker Drive
Suite 902
Chicago, Illinois 60606
(312) 726-8620
FAX (312) 726-1061

900 S. Shackleford Road
Suite 300
Little Rock, AR 72211

P.O. Box 2798
Fullbrook, CA 92088-2798

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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061, HFA-305
Rockville, MD 20852

Docket Number 01N-0397 - Transportation Safety and Potentially Sedating or Impairing Medications

Dear Sir or Madam:

Enclosed please find the comments of Bensinger, DuPont & Associates for submission to the above-referenced docket. Should you have any questions concerning these comments, please do not hesitate to contact me at 1-800-227-8620 or peter.bensinger@bensingerdupont.com.

Thank you for your assistance.

Sincerely,



PETER B. BENSINGER
President
Bensinger, DuPont & Associates

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Department of Health and Human Services

Food and Drug Administration

Transportation Safety and Potentially Sedating or Impairing Medications

Docket Number 01N-0397

Comments submitted by:

Bensinger, DuPont & Associates
20 North Wacker Drive, Suite 920
Chicago, IL 60606

Bensinger, DuPont & Associates (BDA) has long supported efforts to reduce the potential harms caused by alcohol and other drugs, both licit and illicit. It is axiomatic that such efforts must include the protection of transportation safety, which affects the lives and property of all Americans. BDA has promoted the use of drug-free workplace programs for nearly 20 years, and continues to assist transportation employers as they implement such programs. We recognize that compliance with the regulations of the DOT, while important, is not the end of the activities employers should take to prevent substance abuse in their workplaces -- other cost-effective measures should also be taken. For that reason, we have actively encouraged employers to institute company-wide employee assistance programs, among other things.

BDA has reviewed the NTSB recommendations concerning potentially impairing medications. It is clear, as the NTSB notes, that something must be done to more strongly discourage vehicle operators from using impairing medications, especially those available over the counter. Thus,

BDA endorses efforts by the Food and Drug Administration (FDA) to require pharmaceutical companies to prominently label such medications. The label should affirmatively state, in plain and directive language, that the user should not operate a vehicle within twice the dosage interval from the time of taking the medication. The period should be identified in terms of specific number of hours (*e.g.*, if the dosage interval is 4 hours, the warning should proscribe vehicle operation for 8 hours after the medication is taken). The package should also include information on alternative, non-sedating medications that produce the same medical benefits as the potentially impairing substance.

Further, BDA supports the development of a post-accident toxicology program through which testing could be performed after serious transportation accidents for a wide variety of substances. BDA does not, however, endorse the imposition of such a program through a simple expansion of the current, employer-based drug and alcohol testing programs. While such programs are, of course, in general intended to promote safety, they do so by deterring safety-sensitive employees from engaging conduct the proscription of which was already well-supported in law before imposition of any testing program. Thus, post-accident testing in these employer-based programs is not intended to be for the purpose of determining causation. To the contrary, the intent was to provide a triggering mechanism for testing that would add to the deterrence value of the program: *i.e.*, employees would be deterred from using drugs or alcohol by the knowledge that they would be subject to testing should they have the misfortune of being in an accident.

Urine based drug testing is particularly unsuited to cause determinations. Not only can it detect evidence of drug use that occurred hours or days prior to the accident (long after the

psychoactive effects may have dissipated), the test can be performed up to 32 hours *after* the accident. It would be virtually impossible in some cases to discern whether the drug use occurred before or after the accident.

The more logical approach would be to direct DOT to establish a program of public/private partnership through which blood and urine samples could be obtained from individuals involved in a serious transportation accident. DOT would prescribe the circumstances under which testing would be required; advise state and local departments of transportation of testing requirements; identify and certify laboratories capable of performing the testing (or expand the capacity of the Civil Aeromedical Institute laboratory to enable it to handle all specimens) ; and develop and pre-position testing kits with appropriate investigative authorities. The transportation employer's obligations would include: advising employees in writing of testing requirements and the consequences of refusing such tests; and facilitating the completion of specimen collections by investigative authorities. Test results obtained under such a program would be used for investigative purposes, and, if impermissible conduct were identified, could provide the basis for removal of the individual from the performance of safety-sensitive duties.

The most difficult question, of course, is whether to prohibit as a matter of regulation the use of medications not included on a particular list, even with the exception for medically-authorized use. While recognizing that medications could pose a risk to safety under some circumstances, BDA does not believe that this is a feasible approach to the problems identified by the NTSB. Not only would it be hugely burdensome to require the DOT to affirmatively test and identify as "safe" all medications or medication classes, we see no way to effectively enforce such a

regulation. We see no reasonable means through which violations of such a prohibition would be consistently detected. It would be impossible to institute a random testing program of such breadth, and the mere possibility of detection in a post-accident situation is unlikely to be sufficient to deter use of otherwise lawful medications. Sanctions would attach to use of medications only as a matter of happenstance, rather than a consistently applied enforcement program, something that BDA believes would be unacceptable.

In lieu of a prohibition on use of medications, BDA endorses an active program of education about the dangers inherent in medication use, offered to medical professionals as well as to transportation employees through a joint effort of the DOT and FDA. With today's technology, it would be a relatively simple matter to create a web-based program that can be accessed and/or downloaded for use in training, and that can be linked to the websites of organizations such as the Aerospace Medical Association, the American Trucking Association, the AFL-CIO, etc. A concerted effort to educate employers and vehicle operators would be a far more efficacious use of scarce resources than a sanction-based system of prohibitions.

BDA applauds the NTSB and FDA for their efforts to improve transportation safety and appreciates the opportunity to provide comment on this important issue.

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404